X063/38

Antares Ultrasound System Special 510(k) Submission

SECTION 11

510(k) Summary

Prepared 10/11/2006

NOV 2 2 2006

Sponsor:

Siemens Medical Solutions USA, Inc.,

Ultrasound Division 1230 Shorebird Way P.O. Box 7393

Mountain View, California 94039-7393

Contact Person:

Sheila W. Pickering

Telephone:

(650) 943 7187

Fax:

(650) 943 7053

Submission Date:

October 13, 2006

Device Name:

Siemens Antares Ultrasound System

Common Name:

Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class:

П

Review Category: Classification Panel:

Tier II Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550

Product Code 90-IYN

Ultrasonic Pulsed Echo Imaging System

FR # 892.1560

Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892.1570

Product Code 90-ITX

A. Legally Marketed Predicate Devices

The Siemens Antares Ultrasound system is substantially equivalent to the following:

- K052894, K033196, K023729, 1/1/2005, Antares Diagnostic Ultrasound System
- K052021, 8/17/2005, Siemens V5M Transesophageal Transducer
- K011252, 5/30/2001, GE Hitachi EUB 8500 with Sonoelastography

B. Device Description:

The Siemens Acuson ANTARES MODIFICATION has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive

- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

The Antares ultrasound imaging system is intended for the following applications: Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The modifications to the Antares are verified and validated according to the company's design control process as certified in the 510(k) Notification.

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Common Name:

Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class: Review Category:

H Tier II

Classification Panel:

Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550 Ultrasonic Pulsed Echo Imaging System

FR # 892.1560

Product Code 90-IYN Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892.1570

Product Code 90-ITX

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E. Performance Data

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Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Sheila Pickering, Ph.D.
Senior Director of Regulatory Affairs
Siemens Medical Solutions USA, Inc.
P.O. 7393, 1230 Shorebird Way
MOUNTAIN VIEW CA 94039

NOV 2 2 2006

Re: K063138

Trade Name: Siemens ACUSON Antares Modification™ Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO and IYX

Dated: October 13, 2006 Received: October 23, 2006

Dear Dr. Pickering:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Siemens ACUSON Antares ModificationTM Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2 Convex Array C6-2 Convex Array



Protecting and Promoting Public Health

C8-5 Convex Array 5.0C50+ Convex Array C6-3 3D Mechanically Driven 3D Convex Array EV9-4 Convex Array Endovaginal Endo-VII Mechanical Sector Endovaginal Endo-V 3D Mechanical Sector Endovaginal EC9-4 Convex Array Endovaginal BE9-4 Convex Array Endocavity 5.0L45 Linear Array 7.5L70 Linear Array LB5-2 Linear Array L10-5 Linear Array VF13-5 Linear Array VF13-5SP Linear Array 7.5L50I Linear Array 7.5L50Q Linear Array 8L3 Linear Array C7F2 Curved Array LAP8-4 Laparoscopic P4-2 Phased Sector Array 5.0P10 Phased Array MPT7-4 Phased Sector Array TEE CW2 Continuous Wave Doppler CW5 Continuous Wave Doppler P9-4 Phased Sector Array CH5-2 Convex Array V5M TEE

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Page 4-Sheila Pickering, Ph.D.

If you have any questions regarding the content of this letter, please contact Sundar Rajan at (240) 276-3666.

Sincerely yours,

Mancy C. Brogdon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

SECTION 7

Intended Use of the Device

(ACUSON ANTARES ™ Ultrasound System)

Intended Use:

The Acuson Antares ultrasound imaging system is intended for the following applications: Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Intracardiac, Transcsophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

Prescription Use_____

Division Sign-Off)

Division of Reproductive, Abdominal,

and Padiological Devices 530gg number

510(k) Number (if known):

Device Name:

SIEMENS ACUSON ANTARES MODIFICATION TM

Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Feta!		P	Р	P	Р	Þ	P		BMDC	Note 2,3,4,5
Abdominal		P	P	P	P	P	Р		BMDC	Note 2,3,4,5
Intraoperative (Note 6)		P	P	P		P	Р		BMDC	Note 3
Intraoperative Neurological		P	P	Р		P	P		BMDC	Note 2,3
Pediatric		P	P	P	Р	p	Р			Note 2,3,4,5
Small Organ (Note 1)		P	P	Р	P	P	P			Note 2,3,4,5
Neonatal Cephalic		Р	Р	Р	P	P	P		BMDC	Note 2,3
Adult Cephalic	·	P	Р	P	P	Р	P		BMDC	Note 2
Cardiac		Р	P	P	P	P	P		 	Note 2,7
Transesophageal		Р	Р	P	P	P	P			Note 2,3,7
Transrectal		P	Ρ.	P		P	P			Note 2,3,4,5
Transvaginal		P	P	Р		P	P			Note 2,3,4,5
Transurethral									ļ	
Intravascular								·· <u> </u>	-	
Peripheral vessel		Р	P	P	P	Р	P		BMDC	Note 2,3,4,5
Laparoscopic		P	Р	P		Р	Р		22.42.0	Note 3
Musculo-skeletal (Conventional)		P	P	Р	P	P	P	· · · ·	BMDC	Note 2,3,4,5
Musculo-skeletal (Superficial)		P	Р	P	P	P	P			Note 2,3,4,5
Other (specify)							 			

P = previously cleared by the FDA under # K052894) E = added under Appendix E.

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 Virtual Format

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number.

510(k) Number (if

known):

Device Name:

C5-2 Convex Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

		<u>.</u>				Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										İ
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,
Abdominal		Р	P	P		P	P			Note 2,3,4,5,
Intraoperative Abdominal							1			
Intraoperative Neurological								,		·
Pediatric		P	Р	P		P	Р		BMDC	Note 2,3,4,5,
Small Organ										
Neonatal Cephalic				4.1		***				
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		· · · · ·						·		~
Transvaginal		_								
Transurethral								-,		
Intravascular										
Peripheral vessel		P	P	P		P	P	*****	BMDC	Note 2,3,4,5,
Laparoscopic					`		 			2,000 2,0,1,0,
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)								, .		
Other (Specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

N	te .	1	For	example:	breast,	testes,	thyroid,	penis,	prostate,	etc.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if known):

Device Name:

C6-2 Convex Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									Ì	
Fetal		Р	P	Р		Р	P		BMDC	Note 2,3,4,5,7
Abdominal		P	P	Р		P	P		BMDC	Note 2,3,4,5,7
Intraoperative (Note 6)						- 1. i				1
Intraoperative Neurological										
Pediatric		P	Р	Р		Р	P		BMDC	Note 2,3,4,5,7
Small Organ (Note 1)										
Neonatal Cephalic										1
Adult Cephalic				Ī						
Cardiac										
Transesophageal								-		
Transrectal										
Transvaginal										
Transurethral						-				
Intravascular										
Peripheral vessel		P	P	P		Р	P	- "-	BMDC	Note 2,3,4,5,7
Laparoscopic										1
Musculo-skeletal (Conventional)								<u></u>		
Musculo-skeletal (Superficial)										
Other (specify)				1						

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: breast,	testes.	thyroid, r	enis.	prostate, etc.

Note 8 Virtual format

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)/

Division of Reproductive, Abdominal,

and Radiological Devices,

Diagnostic Ultrasound Indications for Use Form

Pg. 6.3 of 6.30

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if

known):

Device Name:

C8-5 Convex Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode	of Operation	3		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	L									
Fetal										
Abdominal		P	Р	P		P	Р		BMDC	Note 3,4,5
Intraoperative (Note 6)	T		<u> </u>						-	
Intraoperative Neurological						<u> </u>				
Pediatric		Р	Р	Р		P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		Р	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic		P	P	P		p	Р		BMDC	Note 3,4,5
Adult Cephalic										
Cardiac		Е	Е	E		E	Е		BMDC	Note 3,4,5,7
Transesophageal										
Transrectal										
Transvaginal	<u> </u>									
Transurethral										
Intravascular	<u> </u>									
Peripheral vessel										
Laparoscopic		<u> </u>								
Musculo-skeletal (Conventional)	<u> </u>	P	P	P	L l	Р	P		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)	ļ .	Е	Е	Е		Е	E		BMDC	Note 3,4,5
Other (specify)										

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- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)/

Division of Reproductive, Abdominal,

and Radiological Devices

Diagnostic Ultrasound Indication (1918) Osumber

Section 6

510(k) Number (if

known):

Device Name:

5.0C50+ Convex Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode o	of Operation			
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										- X - 11 - X - 11 - 12 - 12 - 12 - 12 -
Fetal		Р	P	Р	P	Р	P	-	BMDC	Note 3,4,5
Abdominal		Р	P	P	Р	P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)				Ī						
Intraoperative Neurological						•		· · · · · · · · · · · · · · · · · · ·		,
Pediatric		P	P	P	P	P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		Р	P	P	P	P	Р		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic							1"			·
Cardiac										·····
Transesophageal								*****		
Transrectal						•				
Transvaginal										
Transurethral										
Intravascular						7:0				
Peripheral vessel		Р	P	P	P	P	P		BMDC	Note 3,4,5
Laparoscopic			•						1	
Musculo-skeletal (Conventional)		Е	E	E	Е	Е	Е		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)		E	E	Е	E	Е	E	,	BMDC	Note 3,4,5
Other (specify)										

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- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 Virtual Format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

Diagnostic Ultrasound Indications for Use Number ______

Section 6

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510(k) Number (if

known):

Device Name:

C6-3 3D Mechanically Driven 3D Convex, Array Transducer for use

with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	l		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	P	P		P	P		BMDC	Note 2,3,4,5
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5
Intraoperative (Note 6)						-				
Intraoperative Neurological										
Pediatric		Р	P	P		P	P	***	BMDC	Note 2,3,4,5
Small Organ (Note 1)										
Neonatal Cephalic		Е	E	Е		E	Е		BMDC	Note 2,3,4,5
Adult Cephalic	<u> </u>									,
Cardiac				· · · ·						
Transesophageal										
Transrectal										·
Transvaginal										
Transurethral										
Intravascular	<u>l</u>									
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)							1		1	
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note I	For example:	breast,	testes.	thyroid.	penis.	prostate.	etc.

Note 8 Virtual format

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sigh-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

Diagnostic Ultrasound Indications for Use Point

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Section 6

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if

known):

Device Name:

EV9-4 Convex Array Endovaginal Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										1
Fetal		P	P	Р		P	Р		BMDC	Note 2,3,4,5
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological			<u> </u>							100
Pediatric].							
Small Organ (Note 1)			1							1
Neonatal Cephalic										
Adult Cephalic				1						
Cardiac							1			*****
Transesophageal										7
Transrectal		Р	P	P		Р	P		BMDC	Note 2,3,4,5
Transvaginal		P	P	P		P	Р		BMDC	Note 2,3,4,5
Transurethral						-		***		
Intravascular						·				
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										-
Musculo-skeletal (Superficial)	1			T			1			
Other (specify)		<u> </u>								•

P = previously cleared by the FDA under # K.040060; E = added under Appendix E.

Note 1	For example: breas	st, testes, thyroid,	penis, prostate, etc.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801,109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

Section 6

Diagnostic Ultrasound Indications for Use Form

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

known):

Device Name:

Endo-VII Mechanical Sector Endovaginal Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode of	Operation			
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P						BM	Note 3
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)							-"	·	-	
Neonatal Cephalic		Р	P			-			ВМ	Note 3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P						ВМ	Note 3
Transvaginal		P	P			-,		7.70	ВМ	Note 3
Transurethral						-	-			
Intravascular										
Peripheral vessel	T									
Laparoscopic						*				,
Musculo-skeletal Conventional						·				
Musculo-skeletal Superficial						•		7.1.1		
Other (specify)	1		<u> </u>				1	*******	<u> </u>	

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

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Section 6

Diagnostic Ultrasound Indications for Use Form

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510(k) Number (if

known):

Device Name:

Endo-V 3D Mechanical Sector Endovaginal Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode of	Operation			
Clinical Application	A	В	М	PWD	СWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	P					~	BM	Note 3
Abdominal										
Intraoperative (Note 6)	1					······································		,.		Ì
Intraoperative Neurological			1							
Pediatric										
Small Organ (Note 1)	T									
Neonatal Cephalic		P	Р	1					BM	Note 3
Adult Cephalic										
Cardiac										
Transesophageal				1						
Transrectal		Р	Р			*		~ -	BM	Note 3
Transvaginal		Р	P						BM	Note 3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic						· · · · · · · · · · · · · · · · · · ·				
Musculo-skeletal (Conventional)								43-	<u> </u>	
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast testes	thuroid p	enie proctate	etc
NOW	TOI CAMINDIC,	UI CASL ICSICS.	. uiviuia. D	ems, prostate	. etc.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging Note 5 Power SieScape panoramic imaging Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

known):

Device Name:

EC9-4 Convex Array Endovaginal Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				1		-				
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5
Abdominal									_	
Intraoperative Abdominal								***		-
Intraoperative Neurological										
Pediatric									-	
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic									-	
Cardiac				<u> </u>						
Transesophageal				1						
Transrectal		P	P	P		P	Р		BMDC	Note 2,3,4,5
Transvaginal		Р	P	P		P	Р		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel							1			
Laparoscopic			l	1						
Musculo-skeletal Conventional				1						
Musculo-skeletal Superficial								-		
Other (specify)			, ,	1						·

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801,109)

(Division Sign-Off)

Division of Reproductive, Abdominal

and Radiological Devices

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Diagnostic Ultrasound Indications for Use Form

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510(k) Number (if

known):

Device Name:

BE9-4 Convex Array Endocavity Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	Р	P		Р	P		BMDC	Note 2,3,4,5
Abdominal										•
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric	1						-			
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic								-		
Cardiac					1					
Transesophageal										
Transrectal		P	P	P	1	P	P		BMDC	Note 2,3,4,5
Transvaginal		P	Р	P		P	P		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										-
Peripheral vessel									1	
Laparoscopic					\					
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: I	breast, testes,	thyroid,	penis, prostate, etc.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off))
Division of Reproductive, Abdominal,

and Radiological Devices

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Section 6

Diagnostic Ultrasound Indications for Use Form

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

known):

Device Name:

5.0L45 Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION

Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				I						•
Fetal										
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Small Organ (Note 1)		P	P	P	P	P	P	-1	BMDC	Note 2,3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac									1	
Transesophageal	<u> </u>									
Transrectal										
Transvaginal	1									
Transurethral	T			Γ						
Intravascular				1						
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Laparoscopic										
Musculo-skeletal (Conventional)		P	P.	Р	Р	Р	P	· · · · · · · · · · · · · · · · · · ·	BMDC	Note 2,3,4,5
Musculo-skeletal (Superficial)							****		 	
Other (specify)	T									

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast.	testes, t	hvroid.	oenis.	prostate.	etc.

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

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Section 6

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

B&W SieScape panoramic imaging Note 4

Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Contrast agent imaging Note 7

Note 8 Virtual format

510(k) Number (if

known):

Device Name:

7.5L70 Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

		Mode of Operation								
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		-								
Fetal										
Abdominal										
Intraoperative (Note 6)						******				
Intraoperative Neurological				1			· · · · · · · · · · · · · · · · · · ·			
Pediatric		Р	Р	P		P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P		P	Р		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic									<u> </u>	
Cardiac			1							
Transesophageal					ĺ					
Transrectal										
Transvaginal										
Transurethral					ĺ					
Intravascular								-		
Peripheral vessel		Ē	Е	Е		Е	Ε.		BMDC	Note 3,4,5
Laparoscopic										1
Musculo-skeletal (Conventional)		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)		P	Р	P		P	Р	W	BMDC	Note 3,4,5
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.	Note 1	For example: brea	st, testes, thyroid,	penis, prostate, etc.
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Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if

known):

Device Name:

LB5-2 Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

		Mode of Operation								·
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									ĺ	
Fetal		P	₽	P		P	P		BMDC	Note 4,5
Abdominal		P	P	P		Р	P			Note 4,5
Intraoperative Abdominal							1			,
Intraoperative Neurological							T-10-			· · · · · ·
Pediatric							<u> </u>			
Small Organ									 	
Neonatal Cephalic					_					
Adult Cephalic										<u>-</u>
Cardiac								· · · ·		
Transesophageal							İ			
Transrectal				-						
Transvaginal								16.1		
Transurethral				<u> </u>	-		-			
Intravascular					-					
Peripheral vessel							†			
Laparoscopic						·········	T	-		
Musculo-skeletal Conventional							†			
Musculo-skeletal Superficial	1				7	- nu-				
Other (specify)				<u> </u>						

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note]	For examp	le: breast,	testes,	thyroid,	penis,	prostate,	etc.
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(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if known):

Device Name:

L10-5 Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	10110									
	L					Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic								- 7- Kar	Ì	
Fetal										
Abdominal		P	Р	P		P	P		BMDC	Note 2,3,4,5,8
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		Р	P	P		Р	P		BMDC	Note 2,3,4,5,8
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,8
Neonatal Cephalic		P	Р	P		P	Р		BMDC	Note 2,3,4,5,8
Adult Cephalic										
Cardiac		<u> </u>								
Transesophageal										Ì
Transrectal										
Transvaginal		<u> </u>								· · ·
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Laparoscopic									1	
Musculo-skeletal (Conventional)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,8
Musculo-skeletal (Superficial)		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,8
Other (specify)		<u> </u>	<u> </u>							

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: breast,	testes, thyroid.	, penis, prostate, etc.
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Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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Division of Reproductive, Abdominal,

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Diagnostic Ultrasound Indications cornuse Form

Section 6

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if

known):

Device Name:

VF13-5 Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	e of Operatio	n		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal								_		
Abdominal							· · ·		1	
Intraoperative (Note 6)			1					·		
Intraoperative Neurological	1									
Pediatric		Р	P	P	P	P	P		BMDC	Note 3,4,5,8
Small Organ (Note 1)	T	Р	P	P	Р	P	P		BMDC	Note 3,4,5,8
Neonatal Cephalic		P	P	Р	P	P	P		BMDC	Note 3,4,5,8
Adult Cephalic								••	<u> </u>	
Cardiac										
Transesophageal						-	-	- 11		1/12
Transrectal							<u> </u>	•		
Transvaginal							<u> </u>	· · · · · · · · · · · · · · · · · · ·		
Transurethral				1					-	
Intravascular									1	
Peripheral vessel		Р	P	P	P	P	P		BMDC	Note 3,4,5,8
Laparoscopic										
Musculo-skeletal (Conventional)	1	P	P	P	P	Р	P	-	BMDC	Note 3,4,5,8
Musculo-skeletal (Superficial)		Р	Р	Р	P	P	P		BMDC	Note 3,4,5,8
Other (specify)							"-		1	, ,- <u>,- ,- ,- ,- ,- ,- ,- ,- ,- ,- ,- ,- ,- ,</u>

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast, testes.	thyroid,	penis,	prostate, etc.
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Prescription Use (Per 21 CFR 801.109).

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number __

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

known):

Device Name:

VF13-5SP Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION

Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal							***		1	~
Abdominal							1			
Intraoperative (Note 6)		P	P	P		P	Р		BMDC	Note 3,4,5,8
Intraoperative Neurological		P	P	P		P	Р		BMDC	Note 3,4,5,8
Pediatric		P	Р	P		P	P		BMDC	Note 3,4,5,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5,8
Neonatal Cephalic		P	P	P		Р	P	······	BMDC	Note 3,4,5,8
Adult Cephalic			Ī						1	
Cardiac	T							* **		
Transesophageal										
Transrectal							-			·-
Transvaginal			<u> </u>			-				
Transurethral										
Intravascular				ļ						
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5,8
Laparoscopic		<u> </u>								. , , , , ,
Musculo-skeletal Conventional	1	P	P	P		P	P		BMDC	Note 3,4,5,8
Musculo-skeletal Superficial		þ	P	Р		P	P		BMDC	Note 3,4,5,8
Other (specify)										, , . , . , . , . , . , . , . , .

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast.	testes.	thyroid	nenis	prostate	etc
11000 1	I or example.	or caur,	waw,	tilyit/iu,	DOM:	Di Ostate.	UIV.

Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (QDE)

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Section 6

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if

known):

Device Name:

7.5L50I Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic								-		
Fetal										
Abdominal		Р	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		Р	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic			<u> </u>							-
Cardiac										
Transesophageal										
Transrectal										
Transvaginal			<u> </u>							
Transurethral										
Intravascular							1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7			
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial			Ī							· · ·
Other (specify)	1									

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: I	breast, testes, th	iyroid, penis,	prostate, etc.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal,

and Radiological Devices

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

known):

Device Name:

7.5L50Q Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode o	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal								•		
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		þ	Р	Ь		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	. P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										,
Cardiac										
Transesophageal										
Transrectal										
Transvaginal									1	
Transurethral										
Intravascular								·		
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal (Conventional)		Р	Р	P		Р	P		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)										
Other (specify)				1						

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: breast	testes thyroid.	nenis, prostat	e. etc.
11000	I of Champio, broad	, tooloo, tu fromu,	perno, prostat	·, ····

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal

and Radiological Devices

510(k) Number

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

known):

Device Name:

8L3 Linear Array Transducer for use with:

Siemens Acuson ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ī									
Fetal										
Abdominal		P	P	Р	P	P			BMDC	Note 2,3,4,5,8
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,8
Small Organ (Note 1)		P	Р	Р	P	P	Р		BMDC	Note 2,3,4,5,8
Neonatal Cephalic							4			
Adult Cephalic									-	
Cardiac										
Transesophageal						-				
Transrectal										
Transvaginal										
Transurethral										
Intravascular	Ĭ									
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,8
Laparoscopic										
Musculo-skeletal (Conventional)	1	P	P	P	P	P	Р	· · · · · · · · · · · · · · · · · · ·	BMDC	Note 2,3,4,5,8
Musculo-skeletal (Superficial)				1			1		1	· · · · · · · · · · · · · · · · · · ·
Other (specify)	Ī									

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.	Note 1	For example:	breast, test	es, thyroid,	penis,	prostate,	etc.
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Note 8 Virtual format

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510 (k) Number (if known):

Device Name:

C7F2 Curved array mechanical 3D transducer for use with

Siemens Acuson ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

2						M	ode of Opera	ation		
Clinical Application	А	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal	İ	Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7
Abdominal		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7
Intraoperative Abdominal								-		
Intraoperative Neurological										
Pediatric		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7
Small Organ										
Neonatal Cephalic						·				
Adult Cephalic										,
Cardiac										
Trans-esophageal	Ī									
Transrectal										·
Transvaginal	Ī									
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7
Laparoscopic					L					
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7
Musculo-skeletal Superficial										
Other (specify)										·

N = new indication; P = previously cleared by FDA K033196; E = added under Appendix E

Additional Comments:

- Ensemble tissue harmonic imaging Note 2
- SieClear multi-view spatial compounding Note 3
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- B&W SieScape panoramic imaging Note 7

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdomina

and Radiological Devices

51(Xk) Number

510(k) Number (if

known):

Device Name:

LAP8-4 Laparoscopic Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	L					Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal							`-			·
Intraoperative (Note 6)		P	P	P		P	Р		BMDC	Note 3,4,5
Intraoperative Neurological										1.000 0,1,0
Pediatric										
Small Organ (Note 1)	1							**		- <u>-</u> -
Neonatal Cephalic							T			
Adult Cephalic	1		<u> </u>				"			 .
Cardiac										-
Transesophageal							<u> </u>			
Transrectal	1				-					
Transvaginal										
Transurethral						7	1			
Intravascular								· .		
Peripheral vessel							,			
Laparoscopic		Р	P	Р		P	P		BMDC	Note 3,4,5
Musculo-skeletal (Conventional)							1	ν		0.0 0, 1,0
Musculo-skeletal (Superficial)]									,,,
Other (specify)	ì						1			

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note I	For example:	breast,	testes, th	yroid,	penis,	prostate,	etc.
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Prescription Use (Per 21 CFR 801.109)

(Division Sigh-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

known):

Device Name:

P4-2 Phased Sector Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION

Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	n		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological			_							
Pediatric		P	P	P	P	P	P		BMDC	
Small Organ (Note 1)									1	
Neonatal Cephalic									1	
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3
Cardiac		P	P	P	Р	P	Р		BMDC	Note 2,3,7
Transesophageal										
Transrectal										•
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic] "						† ··-	
Musculo-skeletal (Conventional)								·	1	, '
Musculo-skeletal (Superficial)										
Other (specify)									1	

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast, testes.	, thyroid, p	penis,	prostate, etc.
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Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if

known):

Device Name:

5.0P10 Phased Sector Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal	l	P	P	P	P	P	P		BMDC	Note 2
Abdominal		P	Р	P	Р	P	. P		BMDC	Note 2
Intraoperative (Note 6)]							
Intraoperative Neurological	I	<u> </u>								
Pediatric		P	P	P	P	P	P		BMDC	Note 2
Small Organ (Note 1)										
Neonatal Cephalic		P	P	P	P	Р	Р		BMDC	Note 2
Adult Cephalic					-					
Cardiac		P	P	P	P	P	P		BMDC	Note 2,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular	l									
Peripheral vessel				I						
Laparoscopic										
Musculo-skeletal (Conventional)]						
Musculo-skeletal (Superficial)										
Other (specify)]					

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

N	lote I	Į.	For	example	Ε.	breast,	testes,	thyroid,	penis,	prostate,	etc.
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Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ___

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if known):

Device Name:

MPT7-4 Phased Sector Array TEE Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound

System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic								**************************************				
Fetal												
Abdominal												
Intraoperative (Note 6)]								
Intraoperative Neurological												
Pediatric												
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal		P	P	P	P	P	Р		BMDC	Note 2,3,7		
Transrectal										· · · · · · · · · · · · · · · · · · ·		
Transvaginal										· · · · · · · · · · · · · · · · · · ·		
Transurethral												
Intravascular								-	1			
Peripheral vessel												
Laparoscopic												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Other (specify)												

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast, teste	s, thyroid,	penis,	prostate, etc.
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number.

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

B&W SieScape panoramic imaging Note 4

Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if known):

Device Name:

CW2 Continuous Wave Doppler Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

		· _: L3				Mode of	Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic			Ţ							
Fetal										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)			1							
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Transesophageal										
Transrectal				:						
Transvaginal			1							
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)				Ī						
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

N	ote :	1	For	exampl	e:	breast,	testes,	thyroid,	penis,	prostate, e	ιc.
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Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801,109)

(Division Sign-Off)

Division of Reproductive, Abdomina

and Radiological Devices

510(k) Number ___

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number of

known):

Device Name:

CW5 Continuous Wave Doppler Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION

Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic								****				
Fetal												
Abdominal												
Intraoperative (Note 6)]								
Intraoperative Neurological												
Pediatric												
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac			1									
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral vessel					P					-		
Laparoscopic				I								
Musculo-skeletal (Conventional)						-						
Musculo-skeletal (Superficial)												
Other (specify)]									

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: breast	, testes, thyroid,	penis, prostate, etc.
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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

(Division Sign-Off)

Division of Reproductive, Abdominal.

and Radiological Devices

510(k) Number_

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

B&W SieScape panoramic imaging Note 4

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

known)

Device Name:

P9-4 Phased Sector Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION

Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

					•	Mode of	Operation		 	
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				!						
Fetal		Р	P	P	P	P	P		BMDC	Note 2
Abdominai		P	P	P	P	P	Р		BMDC	Note 2
Intraoperative (Note 6)				-				·		
Intraoperative Neurological		P	P	P		Р	P		BMDC	Note 2
Pediatric		P	P	P.	P	Р	P		BMDC	Note 2
Small Organ (Note 1)		P	P	P	P	Р	Р			
Neonatal Cephalic		P	P	P	P	P	Р		BMDC	Note 2
Adult Cephalic		P	P	P	P	P	P			
Cardiac		Р	P	P	P	P	P		BMDC	Note 2,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral	Ī									
Intravascular										
Peripheral vessel		P	P	Р	P	P	P		BMDC	Note 2
Laparoscopic										
Musculo-skeletal (Conventional)]						_
Musculo-skeletal (Superficial)								1		
Other (specify)										

P = previously cleared by the FDA under # K050240; E = added under Appendix E.

Note 1	For example:	breast, testes,	thyroid, p	enis,	prostate, etc.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sigrl-Off) (()
Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if known):

Device Name:

CH5-2 Convex Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode of	Operation			. 20
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ī]								
Fetal		Þ	P	P		P	P		BMDC	Note 2,3,7,8
Abdominal		P	P	P		Р	P		BMDC	Note 2,3,7,8
Intraoperative (Note 6)									_	
Intraoperative Neurological								-		
Pediatric		P	P	P		Р	P		BMDC	Note 2,3,7,8
Small Organ (Note 1)						,		****		
Neonatal Cephalic									*	
Adult Cephalic										
Cardiac										
Transesophageal				1						
Transrectal										
Transvaginal			T				<u> </u>			
Transurethral								·4-L		
Intravascular							İ			
Peripheral vessel		Р	Р	Р		Р	P		BMDC	Note 2,3,7,8
Laparoscopic		1						***		2,0,7,0
Musculo-skeletal (Conventional)						7,			1	
Musculo-skeletal (Superficial)		Γ								
Other (specify)									<u> </u>	

P = previously cleared by the FDA under # K043016; E = added under Appendix E.

Note 1	.]	ог	example:	breast,	testes,	thyroid,	penis,	prostate, etc.
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Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) / ()
Thyision of Reproductive, Abdominal,

and Radiological Devices

Section 6

Diagnostic Ultrasound Indications for USA Epitumber _

Note 2 Ensemble tissue harmonic imaging

510 (k) Number (if known):

Device Name:

Acuson Antares Diagnostic Ultrasound System

Transducer:

V5M TEE

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

				•			Mode of Opera	tion			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other:
Ophthalmic											-
Fetal						11-1				-	7384
Abdominal		N	N	N	N	· N	N		N*	N	N
Intraoperative Abdominal								11-11		• • • • • • • • • • • • • • • • • • • •	
Intraoperative Neurological								- <u></u>		-	
Pediatric	1	N	N	N	N	N	N	<u> </u>	N	N	N
Small Organ (Specify) **						•			11		- IN
Neonatal Cephalic											
Adult Cephalic					-		-	·			
Cardiac		N	N	N	N	N	N	White and	N*	N	N
Trans-esophageal		N	Ň	N	N	N	N		N*	N	N
Transrectal					-						14
Transvaginal											
Transurethral											
Intravascular										···· -	
Peripheral vessel								-			
Laparoscopic											
Musculo-skeletal Conventional								··	· -	-	
Musculo-skeletal Superficial											
Other (specify)***			-					,			

N = new indication; P = previously cleared by FDA (K032114); E = added under Appendix E

*Combinations include: R.M. R. DWD. R. CWD. R. Galant	D. 1. D. M. G. 1. D
*Combinations include: B+M, B+PWD, B+CWD, B+Color I	Joppler, B+M+Color Doppler, B+CWD+Color Doppler,
B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power	r Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

Diagnostic Ultrasound Indications for Williamber

and Radiological Devices g. 6.30 of 6.30